Summary of Safety and Effectiveness
10/12 Taper Oxinium Femoral Heads
Smith & Nephew, Inc.

APR 1 1 2011

K110101
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Contact Person and Address
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Date of Summary: January 11, 2011

Name of Device: 10/12 Taper Oxinium Femoral Heads
Common Name: Femoral Head
Device Classification Name and Reference: 21 CFR 888.3353 Hip join metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis – Class II
Device Class: Class II
Panel Code: Orthopaedics/87
Predicate Devices: Total Hip Femoral Head – 12/14 Taper (K021673); and Echelon Titanium Hip System (K072817); Smith & Nephew Hip System (K022902); R3 Multi-Hole Shells and 36mm XLPE Liners (K092386); Total Hip Femoral Heads & Liners (K022958)

Device Description
Subject of this Traditional 510(k) Premarket Notification are the Smith & Nephew, Inc. 10/12 Taper Oxinium Femoral Heads. The subject devices are geometrically similar to the femoral head component in the Echelon Titanium Hip System cleared via submission K072817 and will include the addition of 32 mm and 36 mm diameter head sizes. This premarket notification seeks to add the 10/12 taper femoral head in oxidized zirconium material. Oxidized zirconium is the material of manufacture for 12/14 taper Femoral Heads cleared via submission K021673. The subject device will be offered in a size of 22 mm with offsets of -3, +0, and +3 mm; and is sizes ranging from 26 mm – 36mm, all with offsets of -5, +0, and +5 mm.

Intended Use
Total hip components are indicated for individuals undergoing primary and revision surgery where other treatments or devices have failed in rehabilitating hips damaged as a result of trauma, inflammatory joint disease such as rheumatoid arthritis, or noninflammatory degenerative joint disease (NIDJD) or any of its composite diagnoses such as osteoarthritis; avascular necrosis; traumatic arthritis; slipped capital epiphysis; fused hip; fracture of the pelvis; diastrophic variant; nonunion; femoral neck fracture and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques; femoral osteotomy, or Girdlestone resection; fracture dislocation of the hip; and correction of deformity. The subject devices are intended for single use only.

Performance Data
Performance testing of the 10/12 taper Oxinium Femoral Heads yields results at least equivalent to previously cleared devices, Total Hip Femoral head – 12/14 Taper, submission K021673; and Echelon Titanium Hip System, submission K072817. Results of testing and analysis show that the subject device performs equal to or better than previously cleared devices in regards to:

- Pre-Fatigue and Post-Fatigue assembly and disassembly
- Environmental Fatigue and Corrosion
- Axial Fatigue
- Range of Motion
- Device Rigidity, and
- Wear Performance

Substantial Equivalence Information

The substantial equivalence of the 10/12 taper Oxinium Femoral Head is supported by its similarities in design features, overall indications, and material composition to the legally marketed devices for the total hip replacement listed in the following table:

Table 1: Previously cleared devices to which the subject device is substantially equivalent

Description	Submission Number	Clearance Date
Total Hip Femoral Head - 12/14 Taper	K021673	6/11/2002
Echelon Titanium Hip System	K072817	5/15/2008
Smith & Nephew Hip System	K022902	10/2/2002
R3 Multi-Hole Shells and 35 mm XLPE Liners	K092386	11/3/2009
Total Hip Femoral Heads and Liners	K022958	10/2/2002

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Smith & Nephew, Inc.
% Ms. Shereen Myers
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Memphis, Tennessee 38116

APR 1 1 2011

Re: K110101
Trade/Device Name: 10/12 Taper Oxinium Femoral Heads
Regulation Number: 21 CFR 888.3353
Regulation Name: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
Regulatory Class: II
Product Code: LZO
Dated: January 12, 2011
Received: January 13, 2011

Dear Ms. Myers:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K110101 (pg 1/1)

Device Name: 10/12 Taper Oxinium Femoral Heads

Indications for Use:

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Prescription Use	X	AND/OR	Over-The-Counter Use	
(Part 21 CFR 801 Subpart D)			(21 CFR 807 Subpart C)	

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for M. Melkerson

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K110101